

MAR 22 2004

K033694
page 1 of 2

Special 510(k) Notification
INFINITY Modular Monitors with VF4 Modifications

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: November 21, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:

INFINITY Modular Monitors (Delta / DeltaXL / Kappa and
SC 7000 / SC 9000XL / SC 8000)

B. Common Name, Classification Name, Class and Regulation Number:

<u>Common Name</u>	<u>Product Code</u>	<u>Class</u>	<u>Regulation Number</u>
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	II	21 CFR 870.1025
Arrhythmia detector & Alarm	74DSI	II	21 CFR 870.1025

Legally Marketed Device Identification:

INFINITY SC 8000 Monitor, K983632 / K990563
INFINITY SC 7000 / SC 9000XL Modular Monitors, K031340, K003243/K982730/ K980882

Description of Modification:

The VF4 release of the INFINITY Modular monitors supports the "look and feel" of the Draeger Medical product line, including the Draeger logo, colors, menu structure, and physical form. An alarm indicator has been added to the top center of the device that illuminates in red or yellow for the purpose of displaying both life threatening and serious alarms respectively.

Additional minor software modifications have been implemented that primarily address customer requested enhancements.

Testing in accordance with internal design control procedures has verified that the INFINITY Modular Monitors with VF4 modifications are as safe and effective as the previous released versions of the monitors.

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K033694
page 2 of 2

Intended Use:

The INFINITY Modular Monitors are intended for multi-parameter patient monitoring. The devices will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. These devices will connect to an R50 Bedside recorder, either directly or via the INFINITY Network.

Assessment of non-clinical performance data for equivalence:

Verification and validation testing of VF4 software, as well as testing applicable to the hardware modifications for the new Draeger look indicate no new issues relative to safety and efficacy.

Assessment of clinical performance data for equivalence: Not applicable

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: IEEE 802.11
Reviewer Guidance for Premarket Notification 510(k)
Submissions, November 1993



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2004

Draeger Medical Systems, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submission Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K033694
Trade Name: INFINITY Modular Monitors (Delta / DeltaXL / Kappa and
SC 7000 / SC 9000XL / SC 8000)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (two)
Product Code: MHX
Dated: November 21, 2003
Received: November 24, 2003

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Danna R. Vochner

SD Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033694

Device Name: INFINITY Modular Monitors

Indications for Use:

The INFINITY Modular monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Kachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033694

Indications for Use

The SCIO and MultiGas/MultiGas+ modules sample breathing gases from adults and pediatrics. The gas modules continuously measure the content of CO₂, N₂O, O₂ and one of the anesthetic agents, halothane, isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to the INFINITY monitors.

With etCO₂ the monitors can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode; and with etCO₂+Respiratory Mechanics, spirometry and carbon dioxide can be monitored. The monitors can interface with specific third party devices via an MIB protocol converter.

The devices are intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output, ST Segment Analysis, and arrhythmia which are intended for use in the adult and pediatric populations only; and tcpO₂ which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:

The INFINITY Modular Monitors are not compatible for use in a MRI magnetic field.

Diana E. Lochner
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033694